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**The impact of patient-centred versus didactic education programmes in chronic patients by severity. The case of type 2 diabetes mellitus**

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Running title: The impact of education for diabetes patients

Key points for the manuscript entitled “The impact of patient-centred versus didactic education programmes in chronic patients by severity. The case of Type 2 diabetes mellitus”

What is already known about the topic?

- Education improves health-related decisions and is an important component in preventative policy, especially for chronic patients.
- Education programmes are mostly effective for chronic patients including diabetes type 2 patients.
- The design of education programmes for chronic patients has to be cost effective within the transition towards chronic care systems that include the figure of the empowered patient.

What does the paper add to existing knowledge?

- Patient-centred education programmes are more effective than didactic education programmes for type 2 diabetes patients.
- The difference in the benefits between patient-centred and didactic education programmes is not monotonic in the severity (measured by glycaemic control) of patients when initially diagnosed.
- The benefits of attending the patient-centred programme relative to the didactic programme are significant for initially healthy patients, and also for severe patients; we find no difference in the benefits derived from both education programmes in patients with the worst glycemic control.

What insights does the paper provide for informing health care-related decision making?

- Preventative interventions such as patient-centred education programmes are effective for many patients but not enough for all of them.
- In order to attain optimal and cost effective results, it is needed to develop a stratified health policy and find the most effective treatment and education programme for chronic patients depending on their severity, and other alternative interventions for most severe patients.

# **The impact of patient-centred versus didactic education programmes in chronic patients by severity. The case of type 2 diabetes mellitus.**

## **Abstract**

### **Objectives**

Education leads to better health-related decisions and protective behaviours. Patient self-management education programmes have been shown to be beneficial for patients with different chronic conditions, and to have a higher impact on health outcomes than didactic education. However, prior studies have not examined whether the initial severity of the condition is a factor affecting the relative impact of patients attending self-management and didactic education programmes.

### **Methods**

We investigate improvements in glycemic control (measured by HbA1c) on a comparative trial on type 2 diabetes mellitus patients. Our comparative trial involves one group of type 2 diabetes patients receiving patient-centred education and another receiving didactic education. We deal with selection bias issues, estimate the different impact of both programmes and validate our analysis using quantile regression techniques.

### **Results**

We find evidence of better mean glycemic control in patients receiving the patient-centred programme, which engages better patients compared to the didactic programme. However, that differential impact is non-monotonic. Patients initially at the healthy range and who receive the patient-centred programme maintain better their condition. Patients who are close to, but not within, the healthy glycemic range benefit equally from attending either programme. Patients with very high glycemic level benefit significantly more from attending the patient-centred programme. Finally, patients with the worst initial glycemic control (far from the health range) improve equally their diabetes condition, regardless of which programme they attended.

### **Conclusions**

Different patients are sensitive to different categories of education programmes. The optimal, cost effective design of preventative programmes for chronics needs to account for the different impact in different ‘patient categories’. That implies that stratifying patients and providing the appropriate preventative education programme, or looking for alternative policy implementations for unresponsive patients who have the most severe condition and are most costly.

**Keywords:** Patient-centred education; chronic disease self-management; quantile regression.

## Introduction

Education is a key input in the health production function [1]. It leads individuals to take better health-related decisions and more preventative behaviour in diet, exercise, and lifestyle, both for themselves [2,3,4,5] and for their children [6,7]. Empirical studies identify strong correlations between education background and health status [8,9,10], and between income levels and health status [11,12]. Education is especially important for chronic patients or individuals at risk of becoming chronic patients: they suffer (or are at risk of suffering) long-lasting conditions with persistent effects [13] that progressively diminish their quality of life, functional status and productivity [14,15]. Therefore, it is important for chronic patients to learn how to live with their conditions, or for individuals at risk to prevent them. Moreover, the way in which chronic conditions are prevented and treated is of public concern as these currently account for more than 70% of health expenditures [16,17], are estimated to account for 70% of the global disease burden, and will be responsible for 80% of deaths across the world by 2030 [18,19].

Patient self-management education programmes have been shown to be beneficial for patients with different chronic conditions, such as asthma [20], cardiac disease [21], chronic obstructive pulmonary disease [22], and type 2 diabetes [34, 35, 36, 37, 38]. They have the potential to make healthier patients' lifestyle, improve their quality of life, and so, decrease the demand of health services provision and their health expenditures.

In this paper we focus on education programmes for patients with diabetes mellitus (type 2 diabetes). Diabetes mellitus is a chronic disease in which the body fails to create, release and/or respond to insulin, resulting in hyperglycemia (raised blood sugar levels) and systemic damage to many areas of the body including the circulatory system, nervous system and internal organ damage. It is a major source of morbidity and mortality, estimated to affect globally to 9% among adults aged 18 or more [23]. Diabetes is responsible for enormous individual health costs related to direct and indirect effects of hyperglycemia on the human vascular tree. Its impact on patients' life expectancy and health-related quality of life (HRQoL), depends on the severity and duration of hyperglycemia, i.e. the extent by which a person's HbA1c blood sugar

levels lie outside the healthy range (4.0 to 7.0 mmol/l), and the length of time this occurs. In fact, the largest prospective, randomized study to date involving patients with type 2 diabetes (UKPDS35) [24] estimated that each 1% reduction in HbA1c reduces the risk of deaths related to diabetes by 21%, myocardial infarction by 14%, and microvascular complications by 37%. Other studies with data from the US [25,26,27] relate better glycemic control with fewer complications, hospital admissions, and lower health expenditures.

Diabetes is a largely 'self-managed' condition. Day-to-day management is overwhelmingly in the hands of the patient, who must make long-term healthy lifestyle changes involving diet, exercise, and medication. Consequently, the quality of the diabetes education that patients receive shortly after initial diagnosis significantly influences their health choices, promoting the diet, exercise, and the lifestyle changes required to achieve and maintain healthy glycemic levels (i.e. within the 4.0 to 7.0 mmol/l range).

In patient-centred education, self-management plans are developed and maintained through collaboration between patients, who raise their concerns, priorities, knowledge and resources, and the clinical expertise of healthcare professionals. This definition of roles and responsibilities, between patient and healthcare professional, is claimed to increase the intrinsic motivation of diabetes patients to persistently follow agreed plans and attend medical checks [28,29,30,31]. This patient-centred approach is part of a wider shift in health policy for chronic care towards the 'empowered patient' model in many countries, and responds to rapidly rising diabetes-related health costs in national health systems [32,33].

The didactic education model is very different. In the didactic model the patient is a passive recipient of standardized information, provided to all patients. The healthcare professional is an expert who prescribes and defines good practice in diet, exercise and lifestyle choices. Then, the passive patient is expected to adhere to the plans and prescriptions devised by the healthcare expert [34,28].

Hence, it is important to evaluate the impact of different education programmes for diabetic patients. It has been proposed that patient-centred education programmes for type 2 diabetes are more effective than didactic programmes in changing behaviour and ensuring compliance [35,36,37,38,39]. However, empirical evidence on their benefits is

mixed [36,37,40] and different issues have been raised about prior trials. First, they do not directly compare patient-centred and didactic programmes. Rather, control groups have consisted of patients receiving a mix of alternatives, or no formal education at all [37,40]. There might be selection bias since some trials include patients on medication to control their HbA1c. For those, reductions in recorded HbA1c may be due to teaching these patients how to take their prescriptions rather than improvements in diet, exercise and lifestyles. Second, the reporting period is many times too short. The literature finds [36] a difference in HbA1c between groups of 0.92% ( $p = 0.01$ ) six months after the education programme. However, that period is generally considered too short of a period for permanent lifestyle changes to occur [40] and it is commonly agreed that using a reporting period of 12 or 18 months is preferable. Third, there are important differences in the patient-centred programmes in the trials, and there is a lack of consensus regarding the definition of patient-centred programme, its content, or its delivery [41].

Our trial study addresses all the above issues. Furthermore, a novel contribution of our analysis is the application of simultaneous quantile regression analysis. Previous research on diabetes education has not considered whether differential improvements in diabetes control vary across the patient distribution. There are a priori reasons to expect differentials to be non-monotonic. At one end of the distribution are patients who are healthy or close to the healthy glycemic range when initially checked and diagnosed. These may only need to make small lifestyle changes to improve their condition. At the other end are people with the worst health conditions (including obesity). They face the largest challenge in terms of making sustainable, long term changes to diet, exercise and lifestyle. Education programmes, regardless of category, might not have enough impact on these individuals to make them reach the healthy range. This paper contributes to the literature by examining the relative impacts of alternative education programmes across the patient distribution.

## Methods

### *The Salford Trial*

A total of 203 patients with type 2 diabetes were involved in the Salford trial. The trial group received a patient-centred programme; the control group, a didactic education programme. Issues of patient self-selection and General Practitioner (GP) selection were dealt with: in Salford, all patients diagnosed with type 2 diabetes are referred to a specialist education unit and receive a formal education programme within 1 month of diagnosis. In the trial period, patients were randomly selected to attend either the didactic or the patient-centred programme. Of the 203 patients in the trial, 109 received the didactic, and 94 the patient-centred programme. Other issues were taken into account. First, patients receiving medication to control their glycemic levels received education but were excluded from the trial. Second, all patients were drawn from the same set of six GP surgeries conforming the Salford Primary Care Trust to guarantee homogeneity in patients –the city of Salford is a poor socio-economic area with high unemployment, poor housing and social conditions, below national average education attainment, and overwhelmingly white, British ethnic background. Also, the same specialist education team delivered both programmes in the same number of sessions (three two-hours sessions held over three consecutive weeks) freely for patients, at a set of venues that are local to patients within Salford.

In the didactic programme, medical specialists stand in front of the group and deliver the same presentation to all patients attending each session. The same information is provided to all patients who may raise questions. It is not tailored to individual patients. The content of the didactic course provides information on the causes of the condition and symptoms, information on diet and exercise, and foot care. Besides the verbally provided information, patients receive a set of leaflets freely available from the NHS and Diabetes UK.

The Salford patient-centred programme is a ‘mediated learning’ approach based on learning sets applied to groups of 10 to 20 people. Healthcare professionals (trained in a 2 day course) mediate discussions between patients on key areas of diabetes health and self-management. It delivers basic information so that patients can learn to use and critically appraise information on diabetes, how they can translate this information to their own individual circumstances, and learning how best to interact with other patients

who face the same set of issues as themselves. Importantly, patients also learn how to frame questions and engage in an open discourse with healthcare professionals mediating the programme. Consequently, patients gain confidence in voicing their concerns and interacting with healthcare professionals. This set of skills and experiences are not developed in the didactic education programme. The patient-centred programme is supported by an 'education pack' with the same basic information as in the didactic programme but its delivery is patient-centred, and patients are made to reflect on their own current behaviour and health choices. The pack is divided in three sections, with session specific material designed to be read by patients prior to each of them. This initiates the process of patient self-reflection prior to each of the relevant education sessions. Having read the supporting material, and having reflected upon it, patients use the materials as the basis for discussion in their group sessions. The patient-centred programme finalizes with the drawing up of a personal 'Action Plan' with practical steps to change diet, exercise and lifestyle, and the key goals which they will strive to achieve, supervised by the GP.

The difference in marginal costs between the two programmes is small and depends on two components. First, the cost of printed materials provided to patients, which was of £2.00 per pack for the patient-centred programme while in the didactic programme were provided free of charge to the Salford Diabetes Education Team by the NHS and Diabetes UK. Second, the patient-centred programme included a two-day training course for the education team in the mediated learning approaches that underpin the patient-centred programme. The opportunity cost for the two days, based on the wages of the Salford Diabetes Education Team, was £2211.00 (the annual salary of the Team Leader was £51,718 -NHS Band 8B-, the average wage of ten nurses, dieticians and podiatrists was £35,184 -NHS Bands 6 and 7-, and the team administrator wage is £20,804). For the 94 patients attending the patient-centred education programme, the additional cost per patient is £26.00. It is important to note that these marginal costs fall over time, as more patients receive the patient-centred programme, to the limit of £2.00 per patient (i.e. the differential cost of printed materials) when we adopt the perspective of the Salford Diabetes Education Team, or to zero when we consider the societal perspective (under which we take into account that the NHS and Diabetes UK have still to assume the cost of the printed materials for individuals in the didactic programme and that it was equally of £2.00 per pack).



### ***Dataset***

For each of the 203 patients there are two fasting HbA1c scores recorded by the patients' GPs (406 observations): *HbA1c\_Month0* is the fasting glucose level recorded when the patient was first diagnosed with type 2 diabetes. It indicates the patient's diabetes control prior to receiving one or other education intervention. *HbA1c\_Month12* is recorded 12 months after diagnosis, as part of the patient's annual diabetes check-up. It indicates the patient's diabetes control 12 months after the education programme. The dataset includes three demographic variables that are standard control variables: *age* of the patient at the time they attend the education programme; gender (indicated by the dummy variable *female*), and ethnic background (indicated by the dummy variable *white\_eur*).

Table 1 provides descriptives for the variables in the dataset. There are no statistically significant differences in gender, age, or ethnicity of patients attending the two education programmes. Difference in mean female representation in the patient-centred and didactic groups is -0.03 (54% and 57% in the patient-centred and didactic groups respectively). With respect to age, the mean difference between the patient-centred and didactic groups is the same (65.35 with SD: 8.45 in the didactic and 65.8 with SD: 9.69 in the patient-centred). Regarding ethnicity, the means and standard deviations for white European ethnicity are identical because Salford residents are overwhelmingly white European.

The difference of 0.01 mmol/l (at the 5% level) between the mean *HbA1c\_Month0* scores of patients in both programmes is non-significant: 7.759 mmol/l (SD: 1.621) in the patient-centred and 7.749 mmol/l (SD: 1.629) in the didactic, with  $t = -0.0438$  and  $t = -0.0439$  for the two-sample  $t$  test with equal and unequal variances respectively (critical  $t_{0.05; 203} = 1.9718$ ). However, after 12 months, there is a significant difference in *HbA1c\_Month12* scores of -0.325 mmol/l, lower for patients attending the patient-centred programme, at the 5% level: 6.838 mmol/l (SD: 0.859) in the patient-centred and 7.163 mmol/l (SD: 1.009) in the didactic programme, with  $t = -2.4479$  and  $t = -2.4770$  for the two-sample  $t$  test with equal and unequal variances respectively (critical  $t_{0.05; 203} = -1.9718$ ).

In terms of individual and social costs, the estimated mean differences are highly important. The mean glycaemic control of the patient-centred education group is at the upper limit of the healthy glycaemic range in month 12 (6.838 mmol/l) while for the didactic education group it is above that upper limit (7.163 mmol/l). The median score is within the healthy range in both groups although lower for the patient-centred group than for the didactic (6.6 and 6.8 mmol/l respectively). At the same time, the maximum value found in month 12 within patients in the patient-centred group is of 9.3 mmol/l compared to 11.5 mmol/l in the didactic group, which means that the worst patients behave better in the patient-centred than the didactic group, although all of them are still far from the healthy range.

We observe large differences in the within-group changes recorded in months 0 and 12. A 0.7 mmol/l reduction is recorded in the median scores of the patient-centred group (month 12 = 6.6 mmol/l; month0 = 7.3 mmol/l). while this reduction is of 0.6 mmol/l reduction in the median scores of the didactic group (month 12 = 6.7 mmol/l; month0 = 7.4 mmol/l). This difference increases in the distribution for patients with worse glycaemic control, being of 1.2 mmol/l and 0.6 mmol/l at the 75<sup>th</sup> percentile (month 12 = 7.5 mmol/l; month 0 = 8.7 mmol/l for the patient-centred group; and month 12 = 7.9 mmol/l; month 0 = 8.5 mmol/l for the didactic group), and of 4.8 mmol/l and 2.9 mmol/l at the maximum value or worst glycaemic control patient (month 12 = 9.3 mmol/l; month 0 = 14.1 mmol/l for the patient-centred group; and month 12 = 11.9 mmol/l; month 0 = 14.4 mmol/l for the didactic group). We also observe a notable difference in the estimated mean scores. Subject to rounding errors, the mean difference-in-difference (DD) improvement in glycaemic control, over 12 months, for the average patient attending the patient-centred programme, compared to the average patient attending the didactic programme, is 0.335 mmol/l (calculated as  $[7.759 - 6.838] - [7.749 - 7.163]$ ). Table 1 also offers the same statistics for the pooled sample with patients attending both patient-centred and didactic education programmes, with N=203.

[Table 1]

Figure 1 provides quantile plot graphs of the distributions of *HbA1c\_Month0* and *HbA1c\_Month12* scores for both groups of patients including the normal (Gaussian) distribution on the diagonal line. These distributions are not right skewed but have tails

that lie above the diagonal line. Therefore, the distribution matters for the effect of education and deviations from normality lie closer to the centre of the distribution.

[Figure 1]

### ***Estimation analysis***

We apply OLS estimation strategy with fixed effects to test whether there is a statistical difference in the mean improvement in HbA1c control ( $month12 - month0$ ) of patients attending the patient-centred programme relative to those attending the didactic programme ( $pc - didactic$ ). The estimated statistical model is:

$$Diff(HbA1c_i) = \beta_0 + \delta_0 pc_i + \beta_2 olderthan65_i + \beta_3 female_i + \varepsilon_i \quad (1)$$

where the dependent variable  $Diff(HbA1c)$  is the total set of 203 observations with the difference in the blood score at month 0 minus the blood score taken at month 12 for each individual. Our variable of interest is the dichotomous variable  $pc_i$  (patient-centred programme) that takes value 1 when the patient has attended the patient-centred programme and 0 if he has attended the didactic programme. Older than 65 and female are demographic variables, and  $\varepsilon$  is the white noise error term.

A key issue not explored in prior research in diabetes education studies is whether the impact of different education programmes varies across the patient distribution. We estimate, as a robustness check, an OLS model containing a set of dummy variables (equation 2) with coefficients for different ranges depending on the initial glycemic level ( $IG(1)_i=1$  at the healthy range when blood score at month 0 is lower than 7 mmol/l;  $IG(2)_i=1$  when it was high but close to the healthy range when blood score was between 7 and 8.5 mmol/l,  $IG(3)_i=1$  at very high initial glycemic level, when it was between 8.5 and 10 mmol/l; and  $IG(4)_i=1$  at catastrophic initial glycemic level, when blood score was greater than 10 mmol/l at month 0). In this estimation, we will be interested in the coefficients ( $\delta$ ) for the interactions between patient-centred programme and the initial glycemic levels.

$$Diff(HbA1c_i) = \sum_{j=1}^4 \alpha_j IG(j)_i + \sum_{j=1}^4 \delta_j [pc_i * IG(j)_i] + \beta_2 olderthan65_i + \beta_3 female_i + \varepsilon_i$$

(2)

Applying simultaneous quantile regression methods, one can consider, the differential impact on diabetes control of the patient-centred programme at individual points over the conditional patient distribution..

Quantile methods are appropriate where distributions are non-Gaussian or, as here, where there is heterogeneity between segments of the analysed conditional distribution [42]. Quantile regression is a semi-parametric method. The conditional quantile has a linear form but does not impose a set of assumptions regarding the conditional distribution, and minimizes the weighted absolute deviations to estimate conditional quantile (percentile) functions [43,44]. For the median (0.5 percentile), symmetric weights are used. For all other percentiles (e.g., 0.1, 0.2, ..., 0.9) asymmetric weights are employed. By contrast, classical OLS regression minimises the sums of squared residuals in order to estimate models for conditional mean functions.

Quantile regression is preferable to the alternative of segmenting the dependent variable into subsets according to its unconditional distribution and then applying OLS on the subsets because such truncation of the dependent variable can create biased parameter estimates [45]. Because quantile regression employs the full dataset, the sample selection problem does not arise. We deal with the issue of heteroskedacity in standard errors using Gould's bootstrapping procedure [46,47]. Standard errors are obtained via 1000 replications of a panel bootstrap. This is drawn using a fixed initial seed (i.e. 1000), with each individual bootstrapped sample containing the same number of observations as the original sample (i.e. 109 for the didactic and 94 for the patient-centred samples). The software used in all our estimations is Stata 12<sup>1</sup>.

## Results

Table 2 presents the estimated coefficients for our first model. The constant being negative and significant (constant = -0.709; p=0.001), the effect of any type of education is, on average, positive with a fall in HbA1c scores indicating improved

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<sup>1</sup> <http://www.stata.com/stata12/>

glycemic control twelve months after receiving education. Notably, estimated OLS coefficient is -0.338 mmol/l ( $p=0.076$ ) indicating that, on average, patients attending the patient-centred programme better control their diabetes after receiving their programme than control patient group who received a didactic education programme.

Table 2 also provides information on estimated simultaneous quantile regression models at the 25<sup>th</sup>, 50<sup>th</sup> and 70<sup>th</sup> percentiles. In these estimated models, the estimated coefficient is negative but is significant only for the 50<sup>th</sup> and 70<sup>th</sup> percentiles (-0.299 mmol/l ( $p=0.041$ ), and -0.199 mmol/l ( $p=0.077$ ) respectively). This indicates that net gains are non-monotonic.

Age and gender tend not to be statistically significant in the estimated OLS and quantile models in Table 2. This is in line with previous random control trials.

[Table 2]

In order to investigate this further, we estimate an OLS model that contains a set of dummy variables for different ranges of initial glycemic level (healthy, high but close to healthy, very high, and extreme). In this way, one can take into account the initial condition of patients when entering one or other education programme. We estimate the different effect of patient-centred versus didactic education programmes for each range, through the interaction of these dummies and their attendance of one or other programme. Estimates are provided in Table 3a. For individuals within the healthy range, the intercept is not significant, but the patient-centred programme is significantly more beneficial than the didactic programme, with a coefficient of -0.572 ( $p=0.014$ ). For all other ranges of initial glycemic control, with HbA1c greater than 7 mmol/l (high, very high and extreme), the intercept is negative, statistically significant and increasing (-0.495 with  $p=0.004$ ; -1.293 with  $p=0.000$ ; and -3.643 with  $p=0.000$ ).

These results also indicate that education is increasingly beneficial in the initial level of HbA1c in mmol/l, while net difference in the glycemic control of patients receiving a patient-centred education relative to those receiving a didactic programme is non-

monotonic and depends on their initial condition. For individuals with high initial HbA1c but close to the healthy range (7 to 8.5 mmol/l), both programmes are equally effective (i.e. the estimated coefficient is not statistically significant). However, for individuals with a very high HbA1c initial level (between 8.5 and 10 mmol/l), the patient-centred program is more effective in improving the glycemic control than the didactic programme with a coefficient of -0.490 ( $p=0.083$ ). Finally, for individuals with an extreme initial HbA1c level (greater than 10 mmol/l), there is also no statistical difference in glycemic control of patients receiving either programme..

These results are consistent with the predicted difference (Month 0 - Month 12) in the blood scores for the patient-centred compared to the didactic programme shown in Figure 2a, with significant differences at the healthy initial range and also at the third range of very high HbA1c initial level. In the case of the patient-centred programme, the predicted difference is always negative (beneficial) while for the didactic programme it is not.

In order to understand the different effectiveness among both programmes is useful to look at the 35 individuals (8 in the patient-centred and 27 in the didactic) for which the programme has not produced any benefit and their glycemic control has worsened (Figure 2b). For them, the average difference is of 0.425 (patient-centred) and 0.837 (didactic), and is significant for those individuals at the healthy initial range and the only range of initial HbA1c in which individuals at the patient-centred programme worsen more than those at the didactic programme is between 7 and 8.5 mmol/l. Once again, age and gender are not found to be statistically significant.

Table 3b presents the percentage of success, by education programme, in patients achieving a healthy glycemic range after 12 months. The most significant differences are for individuals in the healthy initial level and for those with initial glycemic level between 8.5 and 10 mmol/l.

[Table 3a and Table 3b]

[Figure 2a and 2b]

In order to explore more extensively the different effectiveness of both programmes across the distribution, a set of simultaneous quantile regression models were estimated at 0.05 percentile intervals, from the .05 to the .95 percentile. Table 4 reports the coefficients for the intercept and the patient-centred differential effect for such models (demographic variables were included but not reported as they were mostly non-significant). Results are consistent with our previous estimations. However, it is important to note that, where in the OLS analysis we ascertained the average improvement effects for individuals who started with different glycemic control levels, with the quantile regression we can examine the effects on the q-quantile itself.

We find a non-monotonic relationship across the patient distribution. In the first half of the HbA1c distribution, the difference between the blood scores at Month 0 and 12 is mostly explained by the intercept, which is negative, large, and statistically significant (percentiles 0.05 to 0.50). The differential between effect of the patient-centred programme is negative but non-significant.

Progressing further along the distribution (percentiles 0.50 to 0.90), the differential becomes larger and the effect of education is more often explained by attendance of a specific programme than by the intercept (the receiving of education in general). This indicates that there is a strong effect due to the patient-centred programme for patients within this range.

[Table 4]

Figure 3 shows the coefficients for the intercept and differential effect of the patient-centred programme across the distribution. We see that the net difference in glycemic control is always negative and mostly significant (95% CI) between 50<sup>th</sup> and 90<sup>th</sup> percentiles of the distribution. However, the difference is non-monotonic, decreasing in absolute value between the 50<sup>th</sup> percentile (-0.300; p=0.041) and the 70<sup>th</sup> percentile (-0.200; p=0.077). Above the 70<sup>th</sup> percentile, the differential increases up to the 90<sup>th</sup> percentile (-0.400 with p=0.042), after which the estimated differential becomes non-significant for the remainder of the HbA1c distribution.

## Conclusions

Education leads individuals to take better health-related decisions and more preventative behaviour. Education is thus an important component in preventative health policy, especially for patients with chronic conditions such as diabetes. In this paper we consider two categories of education programmes designed to promote behavioural change to healthier lifestyles amongst people with type 2 diabetes, and thereby prevent or reduce significantly the severity of the complications associated with this condition. In contrast with COPD, cardiac disease, asthma, and type 1 diabetes where there is strong evidence of a relationship between education and improved health outcomes [20,21,22], empirical evidence for type 2 diabetes is mixed [36,37,40].

The empirical results clearly indicate improvements in the mean glycemic control of patients receiving the patient-centred programme after 12 months compared to patients receiving the didactic programme. Based on a well-specified control group, the average effect estimated by OLS is -0.338 mmol/l, at the upper end of previous trials reported in the meta-studies [37,40]. This level of improved metabolic control represents a significant reduction in complications, and improvement in quality of life.

By also applying OLS at different ranges of the glycemic level and quantile regression methods, the current study sheds new light on the effectiveness of education programmes. In particular, it has identified four distinct categories of patient within the diabetes population.

Based on the findings of our study, patients initially at the healthy range need to understand their condition and undertake preventive measures to avoid future complications. For them, patient-centred education is significantly more effective than the didactic programme. In fact, the didactic programme is not effective for those patients as in average they worsen their glycemic control. Hence, healthy patients are not engaged in the didactic programme, do not take seriously education and do not prevent. They should attend patient-centred education. Second, patients with high glycemic level but close to the healthy range are able to make changes in their lifestyles within 12 months. For them, any education programme is effective and beneficial



compared to the alternative of no education. Although results are better for the patient-centred programme the difference is not significant, probably because being close to the healthy range, but already unhealthy, patients enrolled in any program obtain a high rate of success. Third, patients with very high glycemic level need specific education to contribute to their behavioural change. Being far from the healthy glycemic level, engaging patients becomes more important and our findings suggest that, for this category of patient, again, patient-centred education is more effective than didactic education. Finally, for patients with the worst health conditions, including obesity, and, as a consequence, the highest individual health costs, we find that patients receiving patient-centred education do not benefit more than patients receiving didactic education. For this category of patient, aware of his need, both patient-centred and didactic preventative education programmes are very effective in changing lifestyles and improving health choices, and all of them improve their glycemic control even if most of them do not get to the healthy range in 12 months.

Our research findings highlight the need for a stratified health policy. Preventative health policy can be effective for most patients at initially healthy, high or very high glycemic level, and the patient-centre programme presents better results. Our results presents several limitations. First, they are based on our case study with a sample size of 203 individuals. As a consequence, in order to generalize our results and policy recommendations for education programmes, they should be confirmed by similar studies. Also, the focus in our paper is not to develop a full cost effectiveness analysis of the two education programmes. However, prior work on the economic evaluation of diabetes education programmes [48], literature relating improvement in the control of glycemic levels and a lower demand of health services and expenditures [24,25,26,27], and the minimum additional cost per patient (£26.00) of the patient-centred programme point to significant savings in health expenditures for patients in the relatively healthy and intermediate categories at the initial diagnose attending to the patient-centred programme.

However, for the last patient category – made up of patients with the most severe condition - education is effective in improving glycemic control but not in getting patients into the healthy range, and guidelines are required for finding their most effective treatment or complement to education. This may include alternative interventions such as bariatric surgical procedures (gastric banding, gastric bypass, or

sleeve gastrectomy). The cost-benefit implications for health expenditure of surgical procedures such as these are different to preventative health education programmes. Although further research is needed in this topic, our results point to policy stratification as a requirement to achieve an optimal resource allocation, which produces the correct mix of education and other health interventions to different patient categories.

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Table 1. Means, standard deviations, minimum and maximum values, 25th percentile, median and 75th percentile.

		Didactic group	Patient-centred group	Pooled sample
HbA1c_Month0 (mmol/ l)	Mean	7.749	7.759	7.754
	Std. Deviation	1.629	1.621	1.621
	Minimum	5.4	5.5	5.4
	25th perc.	6.7	6.6	6.6
	Median	7.4	7.3	7.3
	75th perc.	8.5	8.7	8.6
	Maximum	14.4	14.1	14.4
HbA1c_Month12 (mmol/ l)	Mean	7.163	6.838	7.012
	Std. Deviation	1.009	0.859	0.954
	Minimum	5.6	5.3	5.3
	25th perc.	6.4	6.3	6.4
	Median	6.8	6.6	6.7
	75th perc.	7.9	7.5	7.7
	Maximum	11.5	9.3	11.5
Age	Mean	65.35	65.35	65.35
	Std. Deviation	8.45	9.69	9.05
Female	Mean	0.54	0.57	0.55
	Standard Deviation	0.5	0.49	0.49
White_eur	Mean	0.99	0.99	0.99
	Std. Deviation	0.1	0.1	0.1
N		109	94	203

Table 2. OLS and quantile regressions on the difference between HbA1c scores of patients attending the patient-centred programme and the control group attending the didactic programme.

Dependent Variable: Difference between the HbA1c blood scores (mmo/l) in Month 0 and Month 12

	OLS		25 <sup>th</sup> percentile		50 <sup>th</sup> percentile		70 <sup>th</sup> percentile	
	Coefficient	Robust S.E.	Coefficient	Robust S.E.	Coefficient	Robust S.E.	Coefficient	Robust S.E.
Patient-centred programme (differential impact relative to didactic programme)	- 0.338*	(0.189)	- 4.77e-07	(0.387)	- 0.299**	(0.145)	- 0.199*	(0.112)
Control variables:								
Female	0.157	(0.192)	0.500	(0.372)	0.299*	(0.163)	1.09e-19	(0.226)
Older than 65	0.052	(0.192)	0.200	(0.338)	0.199	(0.232)	7.42e-17	(0.161)
Constant	- 0.709***	(0.207)	- 1.600***	(0.356)	- 0.599***	(0.873)	- 2.36e-16	(0.172)
N		203		203		203		203
F		1.18						
R <sup>2</sup>		0.0185						
Pseudo R <sup>2</sup>			0.0148		0.0180		0.0090	

\*\*\* p<.01; \*\* p<.05; \* p<.10 Quantile bootstrap reps = 1000.

Table 3a. OLS estimation of the effect of patient-centred programme relative to the didactic programme in the variation of HbA1c blood scores by initial glycemic level.

Dependent Variable: Difference (Month 0 – Month 12) in the HbA1c blood scores (mmol/l)

	Coefficient	Std. Error	P> t
Constant by range of IG			
IG(1): Initial HbA1c < 7 mmol/l	0.182	0.231	0.430
IG(2): 7.0 mmol/l ≤ Initial HbA1c < 8.5 mmol/l	-0.495***	0.169	0.004
IG(3): 8.5 mmol/l ≤ Initial HbA1c < 10 mmol/l	-1.293***	0.195	0.000
IG(4): Initial HbA1c ≥ 10 mmol/l	-3.643***	0.411	0.000
Differential effect (Patient-centred relative to didactic programme)			
IG(1)*patient-centred	-0.572**	0.231	0.014
IG(2)*patient-centred	-0.053	0.180	0.769
IG(3)*patient-centred	-0.490*	0.281	0.083
IG(4)*patient-centred	-0.044	0.585	0.940
Demographic variables			
Older than 65	0.085	0.135	0.532
Female	0.094	0.127	0.458
N	203		
R-squared	0.6847		

\*\*\* p<.01; \*\* p<.05; \* p<.10

IG: Initial Glycemic level

Table 3b. Percentage of patients within the healthy glycemic range by Month 12, according to initial glycemic level (IG).

	Patient-centred	Didactic
IG(1): Initial HbA1c < 7 mmol/l	100.00%	88.57%
IG(2): 7.0 mmol/l < Initial HbA1c < 8.5 mmol/l	62.96%	56.52%
IG(3): 8.5 mmol/l < Initial HbA1c < 10 mmol/l	47.37%	22.22%
IG(4): Initial HbA1c > 10 mmol/l	22.22%	20.00%

IG: Initial Glycemic level

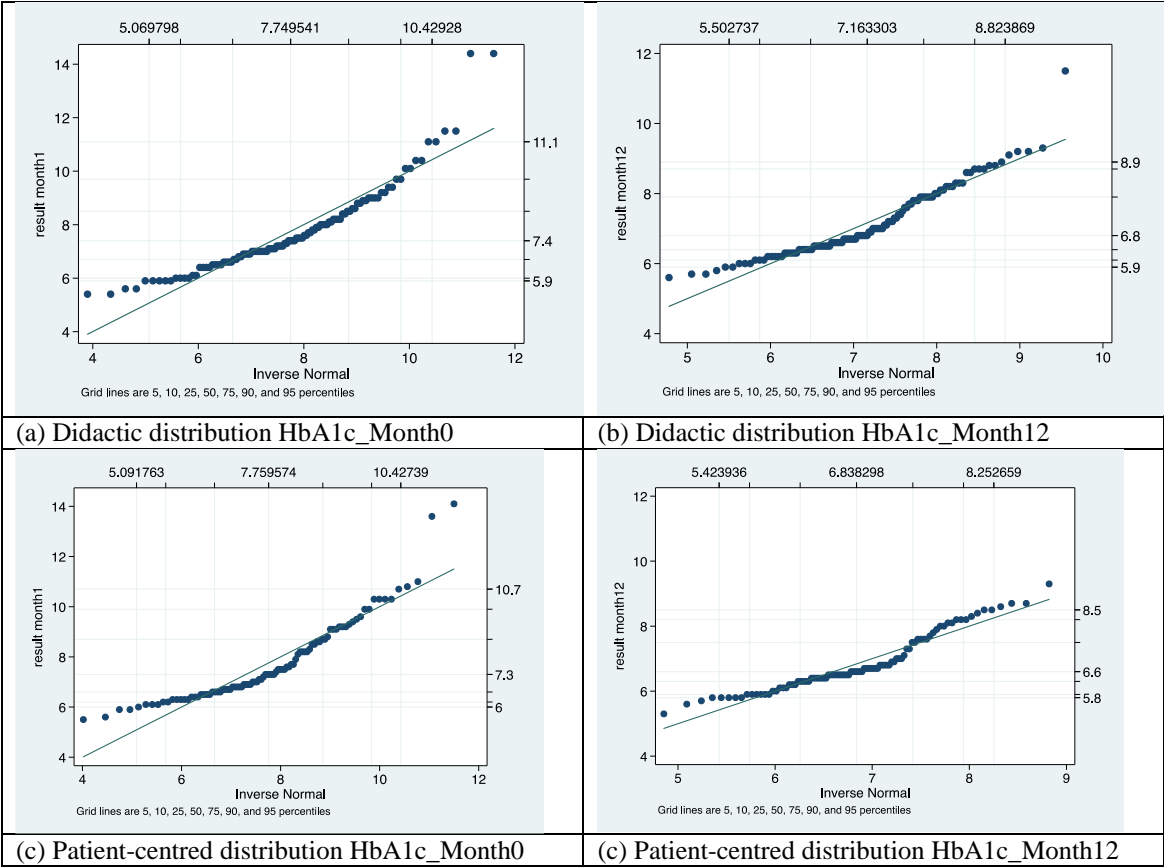


Table 4. Estimates of the differential improvement in glycemic control of patients attending patient-centred compared to those attending didactic programmes, and intercept in the simultaneous quantile regressions: Distribution 5% to 95%.

Percentile	Differential (Patient-centred relative to didactic programme)			Intercept		
	Coefficient	Std. Error	P> t	Coefficient	Std. Error	P> t
0.05	-1.300	0.922	0.160	-2.000**	0.977	0.042
0.1	-0.600	0.575	0.298	-1.900***	0.572	0.001
0.15	-0.300	0.488	0.539	-1.900***	0.406	0.000
0.2	0.000	0.454	1.000	-1.700***	0.380	0.000
0.25	0.000	0.388	1.000	-1.600***	0.357	0.000
0.3	-0.100	0.300	0.740	-1.300***	0.333	0.000
0.35	-0.200	0.228	0.381	-1.100***	0.295	0.000
0.4	-0.200	0.198	0.313	-0.800***	0.247	0.001
0.45	-0.200	0.177	0.261	-0.700***	0.184	0.000
0.5	-0.300**	0.145	0.041	-0.600***	0.142	0.000
0.55	-0.200	0.123	0.106	-0.500***	0.143	0.001
0.6	-0.300***	0.113	0.009	-0.400**	0.172	0.021
0.65	-0.200*	0.113	0.079	-0.200	0.189	0.290
0.7	-0.200*	0.112	0.077	0.000	0.173	1.000
0.75	-0.100	0.112	0.375	0.000	0.153	1.000
0.8	-0.200*	0.111	0.073	0.200	0.150	0.185
0.85	-0.300**	0.116	0.011	0.300*	0.156	0.056
0.9	-0.400**	0.195	0.042	0.500*	0.284	0.080
0.95	-0.800	0.685	0.244	1.000	0.811	0.219

\*\*\* p<.01; \*\* p<.05; \* p<.10

Figure 1. Quantile plots of initial HbA1c scores (in mmol/l) when receiving an education programme (HbA1c\_Month0) and 12 months after programme (HbA1c\_Month12).



N=203 (109 in the Didactic programme and 94 in the Patient-Centred programme).

Figure 2a: Predicted difference in the blood score (in mmol/l) for individuals receiving either the patient-centred or the didactic programme.

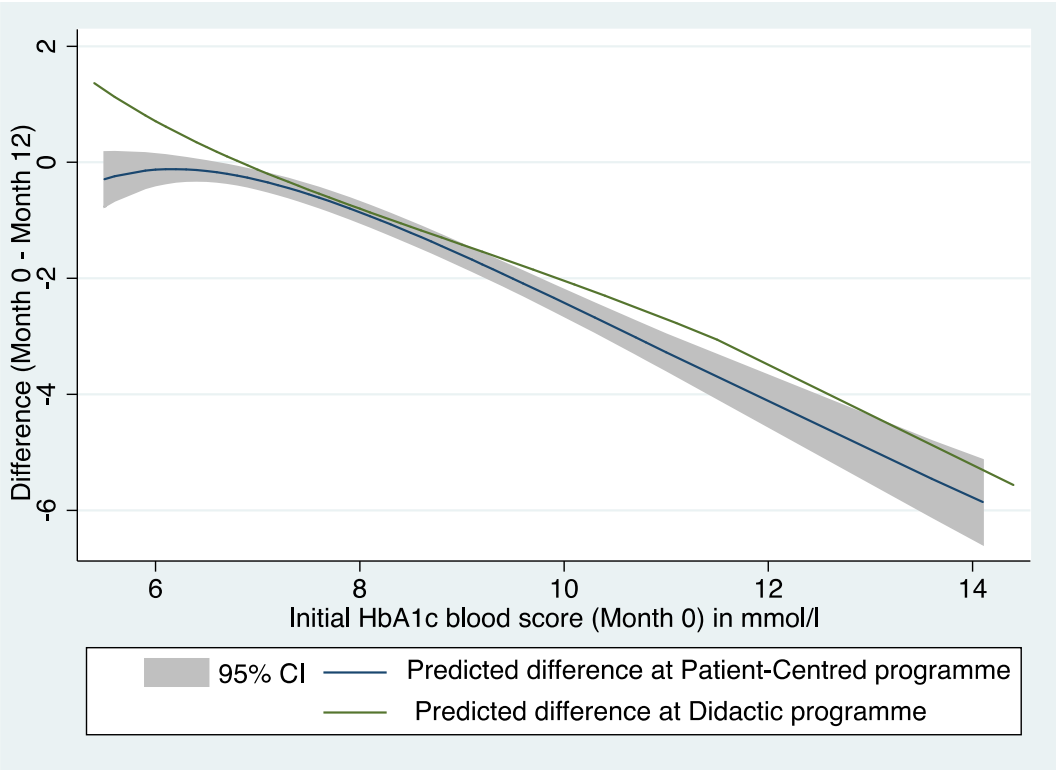


Figure 2b: Predicted difference in the blood score (in mmol/l) for individuals worsening their glycemic control (Month 0 - Month 12) at both the patient-centred and the didactic programme.

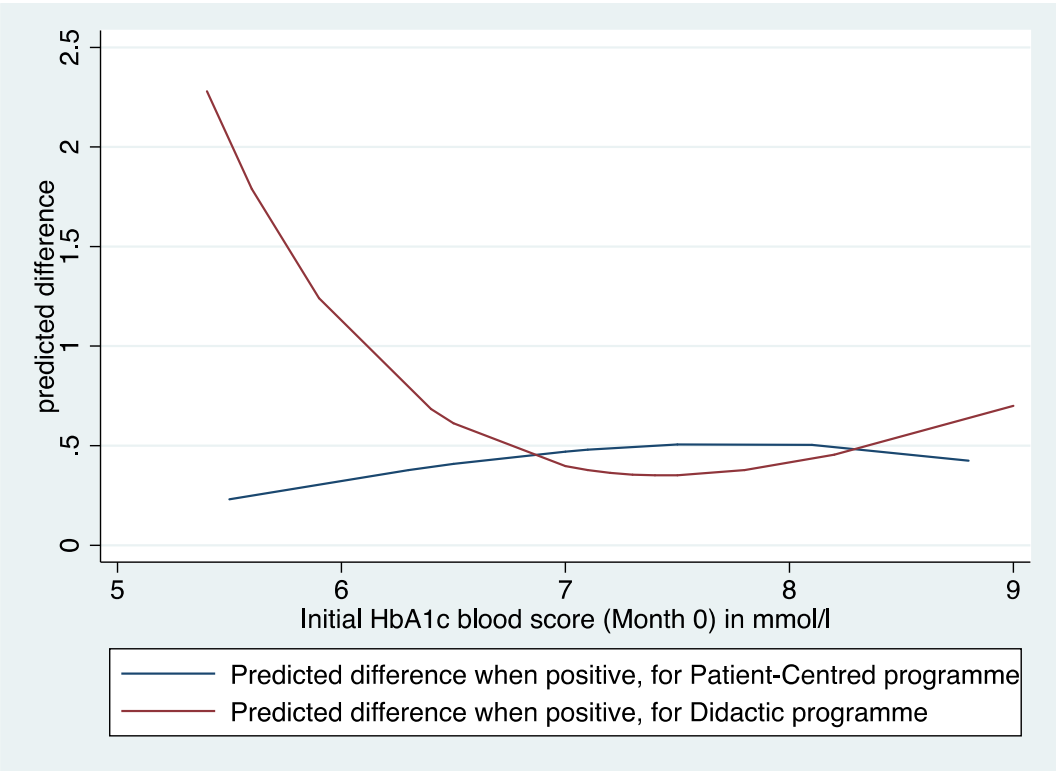


Figure 3. Percentile distribution of the intercept and differential impact of the patient-centred relative to the didactic programme in simultaneous quantile regressions.

Dependent variable: difference in HbA1c blood scores (Month 0 – Month 12).

